K123996
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510(k) Summary

APR 0 9 2013

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: December 21, 2012

Submitter: GE Medical Systems Information Technologies, Inc.
8200 West Tower Ave.
Milwaukee, WI 53223

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Device: Trade Name: RADIAL-CUF Non-Invasive Blood Pressure Cuff

Common/Usual Name: Blood Pressure Cuff

Classification Names: Blood Pressure Cuff

Product Code: DXQ

Predicate Device(s): K120125 Non-Invasive Blood Pressure Cuffs

Device Description: The RADIAL-CUF is a Non-Invasive Blood Pressure cuff that incorporates an inflatable non-distensible bladder, sized to encircle a patient's forearm. Connection tubing allows air to flow in and out of the cuff for inflation and deflation. Inflation allows for the occlusion of the Radial artery. The RADIAL-CUF facilitates the measurement of automated non-invasive blood pressure (NIBP).

Intended Use: Indirect measurement of blood pressure.

Technology: The RADIAL-CUF is based on the cleared SOFT-CUF product line (K120125). Traditional NIBP Cuffs utilize a bladder that is rectangular in shape, to accommodate a limb generally of cylindrical form. The RADIAL-CUF utilizes a bladder of arc form, to accommodate the generally conical shape of the forearm. Cuff materials, tubing and connectors used are identical to those used on the cleared SOFT-CUF product line. The RADIAL-CUF employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The RADIAL-CUF and its applications comply with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the devices:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance Testing (Verification)
- Compatibility – Bench Testing
- Clinical Testing

Summary of Clinical Tests:

To better measure noninvasive blood pressure (NIBP) in special populations, GE Healthcare has designed a new cuff, the GE CRITIKON RADIAL-CUF, for use on the adult forearm. To provide evidence that this new cuff performs properly, a set of studies using the new cuff design was undertaken using subjects who fit the special population demographic requirements.

The first objective for this study was to test the accuracy of the measurements taken with the new cuff on the forearm using the corresponding radial artery as the reference. Two GE Healthcare devices, the GE DASH 4000 with SuperSTAT (NIBP) algorithm and CARESCAPE V100 with Classic NIBP algorithm, were used for the study. The ANSI/AAMI/ISO 81060-2:2009 standard was used as the basis for analysis. The second objective was to evaluate the accuracy of the NIBP measurements using a marketed upper arm cuff used on the forearm.

The DASH 4000 was used for collecting the continuous invasive radial arterial blood pressure and ECG waveform. The DASH 4000 and CARESCAPE V100 collected the NIBP values using the forearm cuff. The noninvasive systolic, diastolic, and mean blood pressures were compared to the invasive data using the requirements detailed in the ISO 81060-2 standard. The forearm data for each of the two NIBP devices were analyzed independently as separate ISO 81060-2 studies. The data comparing the NIBP results using the non-radial marketed SOFT-CUF on the forearm was also analyzed independently from the forearm cuff data.

The results demonstrate that the GE CRITIKON RADIAL-CUF meets the ISO 81060-2 accuracy standards using the DASH 4000 with SuperSTAT NIBP algorithm and the CARESCAPE V100

with Classic NIBP algorithm. The non-radial marketed SOFT-CUF applied to the forearm failed to meet the ISO 81060-2 accuracy standards, as it did not provide accurate radial artery referenced NIBP results when used on the forearm.

In summary, the GE CRITIKON RADIAL-CUF provides accurate radial artery referenced NIBP measurements using GE automatic NIBP devices

Conclusion: GE Healthcare considers the RADIAL-CUF NIBP cuff to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2013

GE Medical Systems Information Technologies, Inc.
c/o Ms. Mary Carter
8200 West Tower Ave.
Milwaukee, WI 53223

Re: K123996
Trade/Device Name: Radial-Cuf Non-Invasive Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: February 25, 2013
Received: February 26, 2013

Dear Ms. Carter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown

Device Name: RADIAL-CUF Non-Invasive Blood Pressure Cuff

Indications for Use:

GE CRITIKON blood pressure cuffs are accessories used in conjunction with noninvasive blood pressure (NIBP) measurement systems. The RADIAL-CUF is intended for use with automated oscillometric NIBP devices to measure radial arterial pressure on the forearm. The RADIAL-CUF is available in adult size only. The device is non-sterile and is semi-disposable (may be single-patient use or optional limited reuse). The cuff is intended for use in patients whose upper arm circumference is greater than 40cm or in patients where currently marketed GE CRITIKON upper arm cuffs cannot be used, due to excess width of the cuff or conical shape of the upper arm. The forearm cuff is intended to be placed on the patient's forearm with circumference ranging from 26cm -36cm. The devices are not designed, sold or intended for use except as indicated.

Prescription Use__X_ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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